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A PROTOCOL FOR A PROSPECTIVE STUDY OF PREGNANCY

OUTCOMES OF OPERATING ROOM NURSES AND NURSE

ANESTHETISTS OCCUPATIONALLY EXPOSED TO

WASTE ANESTHETIC GASES AS COMPARED

TO PSYCHIATRIC NURSES IN THE

UNITED STATES AIR FORCE

by

Ruth L. Nancarrow, R.N., B.A., M.A., Major, USAF, Nurse Corps

THESIS

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Presented to the Faculty of The University of Texas

Health Science Center at Houston

School of Public Health

in Partial Fulfillment

of the Requirements

for the Degree of

MASTER OF PUBLIC HEALTH

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON Houston, Texas June 1980

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To Joyce

A special friend who had the courage to act on her convictions and the concern to inspire others to reach their true potential

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May 19, 1980

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UNITED STATES AIR FORCE

Ruth L. Nancarrow, MPH The University of Texas, 1980

Supervising Professor: Alfonso Holguin

The National Institute of Occupational Safety and Health published a criteria document in 1977 that cited numerous hazardous effects of occupational exposures to waste anesthetic gases, most consistently spontaneous abortion. These experts specifically addressed the need for further research in this area, identifying a prospective study in particular.

This thesis establishes a methodology to link information from the automated personnel data base at the Air Force Military Personnel Center with the information contained in the medical records for those individuals under study. This linkage permits continuous surveillance of an exposed individual throughout the Air Force career and into their separation or retirement if necessary.

The combined data create an epidemiological file for analysis to observe if Air Force nurses, like their civilian counterparts, are at greater risk of spontaneous abortion as a result of their occupational exposure to waste anesthetic gases. Perhaps eventually this system could be applied to all Air Force career fields exposed to hazardous substances.

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CHAPTER I

INTRODUCTION

The Occupational Health and Safety Act of 1970 emphasizes the need to protect the health and safety of workers exposed to an everincreasing number of potential hazards at their workplace. Under the authority of this act, the National Institute for Occupational Safety and Health (NIOSH) is required to develop the criteria for toxic materials and harmful physical agents and substances. Exposure levels are to be defined at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience.

After an extensive review of numerous studies (a portion of which I will summarize later) NIOSH published the criteria document for a recommended standard for occupational exposure to waste anesthetic gases and vapors in March 1977. The recommended standard applies to all workers, including students and volunteers, who are exposed to inhalation anesthetic agents that escape into locations associated with the administration of, or recovery from, anesthesia. Compliance with all sections of the standard should minimize potential adverse effects

of waste anesthetic gases on the health and safety of workers and their unborn children (NIOSH, 1977:2).

NIOSH cautions that the recommended permissible levels of exposure contained in this standard cannot be defined as safe levels yet since information on adverse health effects is not complete and many unknown factors still exist. Therefore, the occupational exposure limits presented should be regarded as the upper boundary of exposure, and every effort should be made to maintain exposures as low as is technically feasible.

The NIOSH recommendation for the maximum permissible concentration of inhalation anesthetic agents is as follows:

- 1. Occupational exposure to halogenated anesthetic agents shall be controlled so that no worker is exposed at concentrations greater than 2 parts per million (ppm), based on the weight of the agent collected from a 45 liter air sample by charcoal adsorption over a sampling period not to exceed one hour.
- 2. Occupational exposure to Nitrous Oxide shall be controlled so that no worker is exposed at time weighted average (TWA) concentrations greater than 25~ppm. (p. 3)

The NIOSH recommendations for attaining the standard include:
low leakage practices by anesthesia personnel to minimize waste gas
concentrations within the operating room, an equipment maintenance program specifically intended to reduce gas leakage from all anesthesia
equipment, collection of anesthetic gases and vapors from the anesthetic circuit and their effective disposal from the workplace

- ' '

(scavenging), adequate ventilation of all areas where inhalant anesthetic agents are employed, air monitoring programs to assess the effectiveness of the preceding measures, and a personnel surveillance program to monitor any adverse effects on exposed personnel. NIOSH recommended that the surveillance program be initiated with the employee's pre-employment physical and continue for twenty years beyond employment.

The Air Force Surgeon General, concerned with the management of this problem, has charged the Air Force occupational health experts with the development of standards for waste anesthetic gases that will apply to all USAF medical facilities. Many Air Force medical facilities have addressed the first five NIOSH recommendations with various degrees of success. The development of an Air Force standard and its subsequent enforcement through Air Force regulations will ensure that waste gas control programs will be implemented Air Force wide. Target date for the standard release is 1 May 1980. However, there is presently no documented program for implementing the last NIOSH recommendation.

A 1975 study by Cohen indicated the magnitude of managing the potential problem by estimating that approximately 20 million patients are anesthetized each year with inhalation anesthetics in the 25,000 hospital operating rooms throughout the country. Approximately

50,000 hospital operating room personnel are exposed daily to waste anesthetic gases in the United States. This figure does not include surgeons who usually do not operate every day nor does it consider the undetermined number of personnel working in anesthesia recovery areas who are exposed to concentrations of anesthetics in the expired air of their patients or those individuals who are not members of the professional organizations included by Dr. Cohen (American Society of Anesthesiologists, American Association of Nurse Anesthetists, Association of Operating Room Nurses, and the Association of Operating Room

In general, current scientific evidence obtained from human and animal studies suggests that chronic exposure to anesthetic gases increases the risk of both spontaneous abortion and congenital abnormalities in offspring of exposed female workers and wives of exposed male workers (Cohen et al., 1971, 1973; Corbett et al., 1973; Knill-Jones et al., 1972). The risk of hepatic and renal disease is also increased among exposed personnel (Cohen, 1974). Effects on the central nervous system (CNS) due to exposure to anesthetics have been associated with headaches, nausea, fatigue, irritability, and impairment of psychological function (Bruce et al., 1976). A few studies have suggested an increased risk of cancer (Corbett et al., 1973).

The current concern over the effects of waste anesthetic gases was prompted by a study of 303 Russian anesthesiologists (Vaisman, 1967). He surveyed 193 male and 110 female anesthesiologists by questionnaire. Ninety-eight percent reported using diethyl ether; 59% nitrous oxide; 28% halothane; and 21% other agents. Scavenging of waste anesthetic gases was not practiced; and, concentration levels of probable exposure were not presented. A high prevalence of headache, fatigue, irritability, nausea, and itching was reported among the group. The author noted that 18 of 31 pregnancies among anesthesiologists 24 to 38 years of age ended in spontaneous abortion. Also, there were two premature births and one child born with a congenital malformation. It was reported that two of the women discontinued working in the operating room because of threatened abortions. The anesthesiologists with complicated pregnancies had exposures of 25 hours/week or more while those with normal pregnancies did not exceed 15 hours/week. As a result of this study Russian anesthesiologists are considered to be working in a hazardous duty area and are paid 20% more than surgeons whose exposure times are less.

One of the most comprehensive and complete human studies was completed by the Ad Hoc Committee on the Effects of Trace Anesthetics of the American Society of Anesthesiologists in 1974 with Dr. Cohen as the chairman. The study was conducted by mailing questionnaires to

49,585 operating room personnel in four professional societies (anesthesiologists, nurse anesthetists, operating room nurses, and operating room technicians); and 23,911 individuals in two other professional societies (general duty nurses and pediatricians). The types of anesthetic agents and concentration levels at which the study groups were exposed were not presented. Approximately 20% of the exposed hospital respondents worked in operating rooms with waste anesthetic gas scavenging devices of unknown efficiency.

Female anesthesiologists, nurse anesthetists, and operating room nurses and technicians in the exposed group (exposure during the first trimester of pregnancy and the preceding year) were subject to a statistically significant risk of spontaneous abortion, 1.3 to 2 times that of the unexposed personnel. There was evidence of increased risk of congenital abnormalities among the live-born babies of the exposed female respondents in the survey. An intragroup analysis of the children of the exposed nurse anesthetists compared with the exposed members of their group indicated an increase in congenital abnormalities of more than 60% in the former group. The exposed female anesthetists showed a twofold increase in congenital abnormalities in their children compared with the unexposed female physician anesthesiologists and female pediatricians. There was also an increase of 25% in the incidence of congenital abnormalities for children of the wives of exposed

physician anesthesiologists. The rates for spontaneous abortions and congenital abnormalities were standardized for smoking habits and age at the time of pregnancy.

An increased occurrence of cancer in the exposed female respondents compared with the unexposed control groups was observed. The increase ranged from approximately 1.3 to somewhat less than twofold greater. Separate analyses by type and location of tumor indicate that, with the exception of leukemia and lymphoma, there is no effect at a particular location or for a specific type of cancer. The increased occurrence of cancer was not verifiable in exposed male respondents.

Hepatic disease was reported 1.3 to 2.2 times more frequently in the exposed female respondent groups compared with the unexposed controls (even after excluding serum hepatitis).

The exposed female groups experienced higher rates of renal disease (pyelonephritis and cystitis excluded) ranging from 1.2- to 1.4-fold in magnitude, but no increased risk of renal disease was observed in male respondents.

In its summary the ASA Ad Hoc Committee stated,

The conclusion that operating room personnel are subject to a health hazard, and that such a hazard is the result of anesthetic gases in the ambient air of the operating room, must be advanced with caution. The findings presented here are survey data, retrospective in nature, obtained by mail, and involve data that are

subject to misinterpretation, misrecollection, and variation due to the experience and education of the respondents. Thus, despite strong support from animal studies, the consistency of our clinical data with results reported in other studies, the internal consistencies in comparison of exposed groups in this study with control groups, and the generally high statistical reliability of the results, there remains the possibility that the increased rates for the exposed groups may be due to some undetected biases. There may be an unknown hazard in these locations which is unrelated to anesthetics. However, based on all the information gathered, the committee concludes that an increase in disease rates in operating room personnel is present, and that exposure to waste anesthetic gases in the operating room is the most reasonable explanation.

A 1976 study by Bruce et al. involved exposing volunteers to 50 ppm of nitrous oxide with and without 1 ppm of halothane. These exposures resulted in degraded performance in audiovisual tasks after two to four hours of exposure. When the exposure was increased to 500 ppm of nitrous oxide, visual perception, immediate memory, and motor responses were degraded. Furthermore, they reported the absence of effects when 25 ppm of nitrous oxide and 0.5 ppm of halothane were administered.

The most relevant information available on current occupational exposure is in the epidemiologic and mortality studies reported between 1967 and 1978. The epidemiology studies conducted among operating room personnel suffer from a lack of quantitatively measured exposure levels and identification of anesthetic agents used. In most cases, workers were exposed to a mixture of agents and possibly to several different agents throughout the day. Environmental measurements placed usual

occupational exposures in operating rooms at 1-10 ppm for halothane and 400-3,000 ppm of nitrous oxide (NIOSH, 1977).

The information summarized in Table 1 is compiled from several studies that show the anesthetic gas inhalation exposure and their effect on animals. In these studies, concentrations of anesthetic gases found in the unscavenged operating room were used as well as those levels far above the occupational exposure levels.

These studies are subject to various interpretations as already indicated by NIOSH and the report of the ASA Ad Hoc Committee. The NIOSH criteria document indicated the following as one of the urgent research needs to assist in understanding the issue of effects of waste anesthetic gases:

A prospective health survey should be conducted to determine the effects of the improved working environment on the possible adverse effects on reproduction among exposed female workers and wives of male workers. This study should be conducted after adequate data have been collected on the extent to which waste gas control programs have been implemented. (NIOSH, 1977)

The Air Force has the potential to develop a model program for implementation of the research suggested by NIOSH. Personnel records for every Air Force member have been fully automated since 1969. Health records are not yet fully automated but a computer-assisted mechanism does exist for some aspects of health care. At the present time there is no direct method to link the two data bases. Such a

TABLE 1

ANESTHETIC GAS INHALATION EXPOSTRES
AND EFFECTS ON ANIMALS

		
Species	Exposure Concentration and Duration	Effect
Rats	*700,000 ppm nitrous oxide for 8 days	Decreased WBC count, alter- ation in RNA/DNA ratio
Guinea Pigs	*10,000 ppm halothane 1-5 times for l hr ea	Focal hepatic lesions hepa- tic necrosis
Rats	*500 ppm halothane, 7 hr/ d, 5 d/wk, 7 wk	Increased liver weight hepatic fatty infiltration
Rats	**10 ppm halothane 8 hr/d, 5 d/wk, 8 wk	Ultrastructural changes in neuronal tissues
Rats	**10 ppm halothane 8 hr/d, 5 d/wk, 8 wk	Ultrastructural changes in liver and kidney tissue
Rats	**8-12 ppm halothane 8 hr/d, 5 d/wk, conception to day 60 of age	Permanent learning deficits and neuronal damage
Rats	**8-12 ppm halothane 8 hr/d, 5 d/wk, after day 60 of age	No learning deficits noted
Pregnant Rats	**10 ppm halothane 8 hr/d, 5 d/wk, throughout pregnancy	Cellular and ultrastructu- ral damage in fetal liver, kidney, and brain tissues
Pregnant Rats	*500,000 ppm nitrous oxide 2, 4, or 6 days	Increased fetal death rate and vertebral anomolies

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TABLE 1—Continued

Species	Exposure Concentration and Duration	Effect
Pregnant Mice	*10,000 or 15,000 ppm halothane for 3 hr on day 12, 13, 14, or 15 of	Increased evidence of cleft palate and limb development defects
Pregnant Hamsters	*600,000 ppm nitrous oxide plus 6,000 ppm halothane for 3 hrs on d 9, 10, or 11 of pregnancy	Increased fetal resorptions (abortions)
Pregnant Rats	X ₁₀₀ , 1,000, and 15,000 ppm nitrous oxide, 8 hr or 24 hr/d during pregnancy	Higher fetal death rates at 1,000 and 15,000 ppm

SOURCE: U.S., Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health, Criteria for a Recommended Standard-Occupational Exposure to Waste Anesthetic Gases and Vapors, HEW Pubn. No. (NIOSH) 77-140 (1977), pp. 184-88.

^{*}Concentration greater than occupational exposure.

^{**}Concentrations within usual occupational exposure.

^{**}Concentrations within and greater than occupational exposure.

linkage would permit a long-term followup of exposed personnel and assist in conducting prospective studies.

This protocol is a design for an epidemiological model to permit the Air Force to establish an epidemiological information system by linking the two data bases and to enable the Air Force to conduct a five-year prospective study of pregnancy outcomes (especially spontaneous abortion) among occupationally exposed operating room nurses and nurse anesthetists and nonexposed psychiatric nurses.

If the study design proposed is implemented by the Air Force, the results could be used to assess the association between hazardous health effects and exposure to waste anesthetic gases in the environment. The medical facility where the hazardous exposure occurred could possibly be detected and the efficiency of scavenging systems, operating room ventilation systems, and anesthesia work practices might be measured. All of these factors would be indicators for increased emphasis on environmental control in the practice of preventive medicine. Perhaps eventually the model could be applied to all career fields where personnel are exposed to hazardous substances.

CHAPTER II

METHODOLOGY

Study Design and Populations under Study

We plan to describe the incidence of spontaneous abortions for three categories of female nurses throughout the Air Force: psychiatric nurses, Air Force Specialty Code (AFSC) 9726, operating room nurses, AFSC 9736, and nurse anesthetists, AFSC 9746 as they become pregnant. The basic design is an observational descriptive study of incidence. If the groups are found similar for other risk factors, an observational cohort design may be possible. Since each nurse is assigned an AFSC and corresponding exposure/nonexposure area on the basis of her choice of education and clinical expertise, the nurses under study cannot be randomly allocated by the investigator; therefore, an observational approach is necessary.

These study populations were chosen because of their relative stability within their professional fields, and they can clearly be separated into exposure/nonexposure areas. Occasionally, an operating room nurse will choose to become an anesthetist but she will still remain in the exposure group although the degree of exposure may be

expected to change slightly. It is unlikely that a pyschiatric nurse will choose to enter the anesthesia exposed environment occupationally or vice versa. An individual must apply to be released from these AFSC's which usually requires additional formal education or Air Force specialty courses. Automated personnel data reports are available to provide a quarterly updated roster of personnel in each AFSC and to detect any change in the AFSC.

All female nurses in the study populations will be identified through the automated personnel record system. A packet containing a letter explaining the purpose and conduct of the study, a privacy act statement/consent form allowing the medical records to be employed, a physician instruction letter, self-addressed envelopes and postcards will be sent to the Medical Records Section of each medical facility employing a nurse in the study population (see Figures 1, 2, and 3).

Sources of selection bias that have been identified include the following:

- 1. All nurses who are confirmed to be pregnant by positive urine tests will be encouraged to participate but inclusion in the study will be strictly voluntary.
- 2. This investigator recognizes that psychiatric nurses in particular who do not have a vested interest in the outcome of the

(Epidemiology Division Letterhead Stationary)

Reply to

Att'n of: (office symbol)

Subject: Epidemiological Study Information Letter

To: Nurse Participants

Extensive research in humans and animals has suggested that exposures to waste anesthetic gases in operating rooms may have adverse health effects on the personnel in those environments. Those effects most commonly identified include: spontaneous abortion, congenital abnormalities, involuntary infertility, renal and hepatic diseases, neurological and learning deficits, and cancer.

You have been identified as either an operating room nurse or nurse anesthetist (exposed group) or a psychiatric nurse (nonexposed group). The Air Force is conducting a five-year study of pregnancy outcomes among both groups of nurses as an indicator of potential health problems within the Air Force. Your work location (assignment history) from your personnel records and current medical and physical exam forms will be evaluated during this study. You will be identified by your social security number, no names will become a part of our permanent computer file.

If you agree to participate, your entrance into the study will begin when a physician has confirmed that you are pregnant or if it is confirmed that you spontaneously aborted prior to confirmation of pregnancy. Please sign the attached Privacy Act/consent form (DD Fm 2005) and request that your physician follow the enclosed instruction sheet.

Your participation and cooperation during this study is most appreciated. If you have any questions please call ______ or write us using an inquiry/response card provided.

SIGNATURE BLOCK Chief, Epidemiology Division

Fig. 1. Nurse participant information letter

(Epidemiology Division Letterhead Stationary)

Reply to

Att'n of: (office symbol)

Subject: Epidemiological Study Information Letter

To: Physician Participants

Extensive research in humans and animals has suggested that exposure to waste anesthetic gases in operating rooms may have adverse health effects on the personnel in those environments. Those effects most frequently identified include: spontaneous abortion, congenital abnormalities, involuntary infertility, renal and hepatic diseases, neurological and learning deficits, and cancer.

This patient has been identified as either an operating room nurse or nurse anesthetist (exposed group) or a psychiatric nurse (nonexposed or control group). The Air Force is conducting a five-year epidemiological study of pregnancy outcomes among both groups of nurses as an indicator of potential health problems within the Air Force.

Your participation and cooperation are essential if the study is to succeed in determining whether or not these individuals are working in a hazardous environment. When you confirm that this nurse is pregnant by positive urinalysis, or if you confirm a spontaneous abortion by pathological diagnosis prior to positive urinalysis confirmation, please complete SF 533 "Medical Record-Prenatal and Pregnancy" and include medication history (especially birth control pills and duration) and a smoking history (amount and duration). Xerox this form and mail it to us in one of the attached envelopes with a Xerox copy of her most recent SF 88 and SF 93 "Report of Medical Exam" and "Report of Medical History." At the termination of her pregnancy please send an updated copy of the SF 533 and copies of the AF 565 "Record of Inpatient Treatment" for both the mother and the infant to our office.

Your participation and cooperation is most appreciated. If you have any questions or comments please call us at ______ or write us using one of the inquiry/response cards provided in this packet.

SIGNATURE BLOCK
Chief, Epidemiology Division

Fig. 2. Physician participant information letter

PRIVACY ACT STATEMENT - HEALTH CARE RECORDS

THIS FURM IS NOT A CONSENT FORM TO RELEASE OR USE HEALTH CARE INFORMATION PERTAINING TO YOU

1. AUTHORITY FOR COLLECTION OF INFORMATION INCLUDING SOCIAL SECURITY NUMBER (\$\$N)

Sections 133, 1071-87, 3012, 5031 and 8012, title 10, United States Code and Executive Order 9397.

2. PRINCIPAL PURPOSES FOR WHICH INFORMATION IS INTENDED TO BE USED

This form provides you the advice required by The Privacy Act of 1974. The personal information will facilitate and document your health care. The Social Security Number (SSN) of member or sponsor is required to identify and retrieve health care records.

3. ROUTINE USES

The primary use of this information is to provide, plan and coordinate health care. As prior to enactment of the Privacy Act, other possible uses are to. Aid in preventive health and communicable disease control programs and report medical conditions required by law to federal, state and local agencies; compile statistical data; conduct research, teach, determine suitability of persons for service or assignments, adjudicate claims and determine benefits, other lawful purposes, including law enforcement and litigation, conduct authorized investigations, evaluate care rendered, determine professional certification and hospital accreditation; provide physical qualifications of patients to agencies of federal, state, or local government upon request in the pursuit of their official duties.

4. WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING

In the case of military personnel, the requested information is mandatory because of the need to document all active duty medical incidents in view of future rights and benefits. In the case of all other personnel/beneficiaries, the requested information is voluntary. If the requested information is not furnished, comprehensive health care may not be possible, but CARE WILL NOT BE DENIED.

This all inclusive Privacy Act Statement will apply to all requests for personal information made by health care treatment personnel or for medical/dental treatment purposes and will become a permanent part of your health care record.

Your signature merely acknowledges that you have been advised of the foregoing. If requested, a copy of this form will be furnished to you.

SIGNATURE OF PATIENT OR SPONSOR	SSN OF MEMBER OR SPONSOR	DATE
	1	

DD 1 FEB 76 2005

PREVIOUS EDITION IS OBSOLETE

-48-16-63743 1 0

study may object to scrutiny of their medical records and therefore choose not to participate in the study.

3. Married nurses are more likely to become pregnant and choose to remain pregnant than single nurses.

However, I decided to identify the medical records of all nurses in the study populations initially rather than just those who are listed in the quarterly roster as married in order to allow for changes in marital status that may result in pregnancy but may not appear as a status change in the personnel files until the next quarter. Stratification on multiple variables and application of the results only to the populations studied within the Air Force will strengthen the representativeness of the study.

An example of the study size potential can be approximated from personnel rosters as of 31 December 1979 which follow:

Psy. N. (9726)--87 total females, 24 married Or. N. (9736)--183 total females, 50 married N. An. (9746)--79 total females, 9 married

Operational Definitions

Waste Inhalation Anesthetic Gases and Vapors—are those which are released into work areas (operating rooms, recovery rooms, delivery rooms, or other areas where workers may be subject to job-related exposures) associated with, and adjacent to, the administration of a gas for anesthetic purposes, and includes both gaseous and volatile liquid agents. Herein referred to as waste anesthetic gases (NIOSE: 1077. 2).

Occupational Exposure to Waste Anesthetic Gases—includes exposure to any inhalation anesthetic agent that escapes into locations associated with, adjacent to, anesthetic procedures. Such locations shall include, but shall not be limited to, operating rooms, delivery rooms, labor rooms, recovery rooms, and dental operatories (NIOSH, 2).

Spontaneous Abortion--unintentional loss of the products of conception at twenty (20) weeks gestation or less, confirmed by pathological diagnosis or subsequent negative pregnancy test.

Air Force Medical Care/Pregnancy Policy--a pre-entrance physical exam and medical history are required prior to commissioning and are repeated at least every two years; Pap smears are required annually. All active duty military personnel receive full medical care provided to them for less than five dollars daily. If an active duty Air Force nurse becomes pregnant and leaves the service, she is still eligible for prenatal care and delivery in an Air Force hospital. It has been standard practice for all active duty nurses to be admitted to the hospital for spontaneous abortions. This admission policy provides for standardized care of all subjects under study and affords the opportunity for confirmation of the diagnosis by pathology or negative pregnancy test. Adherence to this policy will avoid the criticism leveled against the Environmental Protection Agency for their report of the Alsea II study--EPA did not consider the admission/treatment policies of various physicians and clinics and were thus accused of possible misrepresentation of data (Lamm: 1979, 23).

Information System--the operations, personnel, and equipment required for the collection, preparation, processing, and distribution of information where processing takes place on an electronic digital computer (HEW, PHS:1972, 39).

 $\underline{\text{Card}}$ --a fairly stiff paper card with twelve rows and eighty columns. Combinations of punched holes represent digits, letters, and characters (p. 310).

Card Deck--a stack of such cards which can be used to input information into a computer (p. 310).

Coding--the preparation of a necessary set of instructions requiring the computer to perform certain functions (p. 310).

Computer—the self-contained portion of a data processing system which is capable of accepting information, processing it according to prescribed instructions, and supplying the answers for which it was programmed (p. 310).

Data Base--the accumulation of facts which provide an adequate reference against which incoming data may be compared (p. 310).

<u>Data File</u>--a data base which is stored in a memory component of the computer system (p. 310).

<u>Disk Memory</u>—a random access information storage bank, separate from the core memory where it is possible to bulk store data (p. 310).

<u>Flow Chart</u>—the use of stylized symbols to represent graphically (usually in block diagram form) a sequence of operations such as "document produced," "information transferred," and so forth (p. 310).

Hard Copy--any type of printed or permanently punched (visually readable) document produced by a computer system (p. 310).

Input--the data or question fed into the computer for processing (p. 310).

<u>Keypunch</u>—a typewriter-like device used to punch holes in cards to represent letters, numbers, or symbols. These holes may be detected electrically by wire brushes or photoelectrically by photocells, or mechanically by metal "fingers" (p. 311).

<u>Line Printer</u>—a device for printing an entire line of characters on hard copy in one action (p. 311).

Machine Readable--data prepared in a form to which the computer can respond, such as a punched card (p. 311).

Offline--any peripheral, ancillary, or remote device which is not, at that precise moment, directly communicating with the computer (p. 311).

Output--the result(s) produced by the computer in response to what it has been instructed (programmed) to perform. This may be a

visual display (similar to television), a set of numbers or tables, typed or printed material, tapes, or card decks (p. 311).

<u>Program</u>—the complete set of instructions and routines given to a computer to enable it to solve a problem. This may include such things as the raw data, the manner in which it is to be processed, and the format in which the answer will be given (p. 311).

Random Access--a technique by which information can be stored in or retrieved from a computer memory without sequentially searching the entire memory file.

Software--the program required to instruct the computer on how problems are to be solved (p. 311).

Data Collection

The data controller/programmer assigned to the study team in the Epidemiology Division, Brooks Air Force Base, Texas, will have a roster of the names and social security numbers (SSN) of all female nurses in the 9726, 9736, and 9746 career fields from the Air Force Military Personnel Center (AFMPC) at Randolph Air Force Base, Texas. This list will be updated quarterly with additions and deletions in each AFSC and it will be current at the beginning of each fiscal year. The quarterly reports of deletions will be kept on file for the duration of the study plus five years in order to establish a retrieval system for those who separate or retire from the Air Force should we have reason to contact them later.

At the time the individual nurse is confirmed pregnant, the physician at her medical facility always completes SF 533, "Medical

Record-Prenatal and Pregnancy" (Appendix, p. 65). This form will be the source document to gather the identifying data and the confounding medical variables such as: name, date of birth, SSN, history of spontaneous abortion, therapeutic abortion, or diagnostic D&C; use of IUD's or birth control pills, alcohol and medications; smoking habits, blood type and Rh factor, parity, nutritional status, and a history of congenital anomalies, stillbirths, infertility problems or use of infertility drugs, metabolic or infectious diseases, thrombophlebitis, or hypertension. The form also indicates the estimated gestational age at the time of the initial exam and an approximate Estimated Date of Confinement (EDC). This form will be stamped with the nurse's outpatient addressograph plate to assure consistent, legible identifying information and then Xeroxed and sent with a copy of the most recent physical exam and medical history forms, SF 88 and 93 (Appendix, pages 59 and 61) and the consent statement, DD Form 2005 (Fig. 3) in one of the self-addressed envelopes to the data collection office in the Epidemiology Division, Brooks AFB, Texas. Submitting any locally produced history forms such as appear in Appendix, page 63 will be encouraged.

When received, the data controller will cross-reference the medical history identification with the personnel roster to assure that the individual is a bonafide member of the study population. The data controller will extract appropriate data from the medical forms by hand

using a predetermined keypunch input data code sheet (Figs. 4 and 5).

This data will be keypunched on cards, entered into the computer, and put into disk storage offline for random access as needed.

The data controller will then use the individual's SSN as the link to request the following personnel data on a computer printout from AFMPC: date married, date entered active duty Air Force, AFSC's and the dates assigned, any change in the AFSC and the duration of the change, length of health institution employment in exposure or non-exposure areas prior to entry on active duty, and her assignment history including her present location. The information will be tabulated, keypunched, and computerized in the same manner as the medical information (Figs. 6 and 7).

At the termination of pregnancy, another copy of the SF 533 and a copy of the AF Form 565 "Record of Inpatient Treatment" (Appendix, p. 67) for both the mother and infant (when applicable) will be forwarded to the data collection office. The information on the AF Fm 565 provides the numerical classification of pregnancy outcome utilizing the International Classification of Disease, Applied (ICDA) code system. The ICDA code will also reflect any complications if encountered. The final SF 533 will reinforce or provide a quality control measure for these data since it would also reflect complications associated with

Social Security Number

$$\frac{1}{1}$$
 $\frac{2}{2}$ $\frac{3}{3}$ $\frac{4}{4}$ $\frac{5}{5}$ $\frac{6}{6}$ $\frac{7}{8}$ $\frac{8}{9}$

Marital Status (unmarried -0, married -1)

Date of Birth (Mon/Yr) $\frac{11}{11} \frac{1}{12} \frac{1}{13} \frac{1}{14}$

Gestational Age at Time of Initial Exam (Wks) $\frac{}{20}$

Estimated Date of Confinement (Mon) $\frac{}{22}$ $\frac{}{23}$

Subject's Blood Type (A -0, B -1, AB -2, 0 -3) $\frac{1}{24}$

Partner's Rh Factor (NEG -0, POS -1) $\frac{}{26}$

Medical Factors (None -0, Thrombophlebitis -1, Hypertension -2, Diabetes -3, Sickle Cell -4, Lupus -5, Cardiac -6, Respiratory -7, Infertility History/Treatment -8.

$$\frac{}{27}$$
 $\frac{}{28}$ $\frac{}{29}$ $\frac{}{30}$

Surgical Procedures and Date Prior to Confirmed Pregnancy: None -0, Cesarean Section -1, Diagnostic D&C -2, Oopherectomy -3, Ovarian Wedge Resection -4, Tuboplasty -5, Spontaneous Abortion (D&C) -6, Therapeutic Abortion -7, Other GYN Surgery -8.

< 6 mos prior -0, 6 mos < 12 mos prior -1, 12 mos < 2 yrs -2,
2 yrs < 3 yrs -3, 3 yrs < 5 yrs -4, 5 yrs < 10 yrs -5, > 10 yrs -6

Procedure 31	Date	Procedure ${33}$	Date
Procedure 35	Date36	Procedure 37	Date

Previous Obstetrical Complications (None -0, Stillbirth -1, Congenital Anomaly -2, Maternal -3, Other Infant -4) $\frac{}{39}$ $\frac{}{40}$ $\frac{}{41}$

Type Congenital Anomaly (ICDA Code) $\frac{}{42}$ $\frac{}{43}$ $\frac{}{44}$ $\frac{}{45}$ $\frac{}{46}$ $\frac{}{47}$ $\frac{}{48}$ $\frac{}{49}$

Previous Maternal Complications (ICDA Code) $\frac{}{50}$ $\frac{}{51}$ $\frac{}{52}$ $\frac{}{53}$

<u>54</u> <u>55</u> <u>56</u> <u>57</u>

Previous Infant Complications (ICDA Code) $\frac{}{58}$ $\frac{}{59}$ $\frac{}{60}$ $\frac{}{61}$

 $\frac{1}{62}$ $\frac{1}{63}$ $\frac{1}{64}$ $\frac{1}{65}$

Use of I.U.D. (No -0, Yes -1) $\frac{}{66}$

Duration of Use (Same Time Factors as Above) $\frac{}{67}$

Use of Birth Control Pills (Yes, -1) $\frac{}{68}$

Smoking History (Never Smoked -0, Quit -1, Still Smokes -2)

Smoking Amount (< 1/2 ppd -0, 1/2 < 1 ppd -1, 1 < 2 ppd - 2, > 2 ppd -3) $\frac{}{71}$

Smoking Duration (< 1 yr -0, 1 yr < 5 yr -1, 5 yr < 10 yr -2, 10 yr < 15 yrs -3, > 15 yrs -4) $\frac{}{72}$

Date Info Keypunches (D/M/Yr) $\frac{}{73}$ $\frac{}{74}$ $\frac{}{75}$ $\frac{}{76}$ $\frac{}{77}$ $\frac{}{78}$

File Code (Medical -1, Personnel -2) $\frac{1}{79}$

Card Number per Individual $\frac{1}{80}$

Fig. 4. Data input code sheet--medical card 1

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Social Security Number $\frac{}{1}$ $\frac{}{2}$ $\frac{}{3}$ $\frac{}{4}$ $\frac{}{5}$ $\frac{}{6}$ $\frac{}{7}$ $\frac{}{8}$ $\frac{}{9}$

Date of Birth or Other Pregnancy Outcome (D/M/Y) $\frac{10}{10}$ $\frac{1}{11}$ $\frac{1}{12}$ $\frac{1}{13}$ $\frac{1}{14}$ $\frac{1}{15}$

Current Pregnancy Outcome (ICDA Code) $\frac{1}{16}$ $\frac{1}{17}$ $\frac{1}{18}$ $\frac{1}{19}$ $\frac{20}{20}$ $\frac{21}{21}$ $\frac{22}{23}$

Maternal Complications (ICDA Code) $\frac{}{24}$ $\frac{}{25}$ $\frac{}{26}$ $\frac{}{27}$ $\frac{}{28}$ $\frac{}{29}$

 $\overline{30}$ $\overline{31}$ $\overline{32}$ $\overline{33}$ $\overline{34}$ $\overline{35}$

Infant Complications (ICDA Code)

 $\overline{36}$ $\overline{37}$ $\overline{38}$ $\overline{39}$ $\overline{40}$ $\overline{41}$

 $\overline{42}$ $\overline{43}$ $\overline{44}$ $\overline{45}$ $\overline{46}$ $\overline{47}$

Date Initial SF 533 Received at Epidemiology Division (D/M/Y)

 $\frac{1}{48}$ $\frac{1}{49}$ $\frac{1}{50}$ $\frac{1}{51}$ $\frac{1}{52}$ $\frac{1}{53}$

Date Most Current SF 88 and 93 on File (D/M/Y)

 $\frac{1}{54} \quad \frac{1}{55} \quad \frac{1}{56} \quad \frac{1}{57} \quad \frac{1}{58} \quad \frac{1}{59}$

Date Final SF 533 and AF 565 Received at Epi (D/M/Y)

 $\overline{60}$ $\overline{61}$ $\overline{62}$ $\overline{63}$ $\overline{64}$ $\overline{65}$

Medical Facility Followup Date (D/M/Y)

 $\overline{66}$ $\overline{67}$ $\overline{68}$ $\overline{69}$ $\overline{70}$ $\overline{71}$

Date Info Keypunched
$$(D/M/Y)$$

$$\overline{72}$$
 $\overline{73}$ $\overline{74}$ $\overline{75}$ $\overline{76}$ $\overline{77}$

File Code (Medical -1, Personnel -2)
$$\frac{1}{79}$$

Card Number per Individual
$$\frac{2}{80}$$

Fig. 5. Data input code sheet--medical card 2

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tore Branch a

Social Security Number $\frac{}{}$ $\frac{\phantom{0$

Date Married (D/M/Y) $\frac{10}{10} \frac{1}{11} \frac{1}{12} \frac{1}{13} \frac{1}{14} \frac{1}{15}$

Primary AFSC $\frac{}{16}$ $\frac{}{17}$ $\frac{}{18}$ $\frac{}{19}$ Secondary AFSC $\frac{}{20}$ $\frac{}{21}$ $\frac{}{22}$ $\frac{}{23}$

Tertiary AFSC $\frac{}{24}$ $\frac{}{25}$ $\frac{}{26}$ $\frac{}{27}$ Duty AFSC $\frac{}{28}$ $\frac{}{29}$ $\frac{}{30}$ $\frac{}{31}$

EAD (Entrance on Active Duty) Date (D/M/Y) $\frac{}{32}$ $\frac{}{33}$ $\frac{}{34}$ $\frac{}{35}$ $\frac{}{36}$ $\frac{}{37}$

Number of Months Occupationally Exposed to Anesthesia Prior to EAD

38 39

Date Primary AFSC Assigned (D/M/Y)

 $\frac{1}{40}$ $\frac{1}{41}$ $\frac{1}{42}$ $\frac{1}{43}$ $\frac{1}{44}$ $\frac{1}{45}$

Educational Programs Attended in Residence--(None -0, Flight School -1, Anesthesia School -2, Operating Room Supervisor Course -3, Nursing Service Management -4, AFIT Bachelor's -5, AFIT Master's -6, SOS -7, ACSC -8, CDC-Infection Control -9)

<u>School</u>	Mon	/Yr	Ente	red
46	47	48	49	50
51	52	53	54	55
56	57	58		60
61	62	63	64	65
66	67	68	69	70

Open (71-72)

Keypunch Date (D/M/Y)

$$\overline{73}$$
 $\overline{74}$ $\overline{75}$ $\overline{76}$ $\overline{77}$ $\overline{78}$

File Code (Medical -1, Personnel -2) $\frac{2}{79}$

Card Number per Indiv' ual $\frac{1}{80}$

Fig. 6. Data input code sheet--personnel card 1

Social Security Number		- 3	<u>_</u>		<u>-</u>	7		9
Chronological Assignment Base (TRIMIS Code (Durat	Histo	ry fr	om E	AD t	o Pr			
$\overline{10}$ $\overline{11}$ $\overline{12}$ $\overline{13}$	14	15		16	17	18	19	
	_						_	
					_	_	-	
					_	-		
		-			_		69	
Open (70-72)								
Keypunch Date (D/M/Y) ${73}$	74	75 7	7 6 7	7 7	8			
File Code (Medical ~1, Pe	rsonn	el -2		9				
Card Number per Individua	1		8	ō				

Fig. 7. Data input code sheet--personnel card 2

delivery or during the prenatal period. This medical information will be computerized as mentioned before.

Data Analysis

Although the information will be keypunched in sequential columns, the computer will be programmed to leave two spaces between each information field when it is line printed as a hard copy. Missing information will be coded with an "X" and contact made with the originating medical facility in order to get it. The computer will also be programmed to sort and tabulate variables and to match variables between the medical and personnel data bases such as the date of birth and the AFSC that will enable us to stratify the population of each AFSC into ten-year age groups (20-29, 30-39, 40+). The computer will also furnish a hardcopy printout of data by exception, for example, all single nurses who are pregnant or all nurses with a prior history of spontaneous or therapeutic abortions. The computer will provide a list of those nurses with an EDC in the quarter to assist in followup action. For example, tracer action will begin if the final copy of the SF 533 and AF Fm 565 were not received by the end of the due month.

The data will be presented in frequency tables for qualitative analysis to show comparability on the confounding variables between the nonexposed (9726) and exposed (9736,9746) groups. The means of each

parameter studied for each AFSC will be compared using a "t" or "F" test with a level of significance of < .05 (Tables 2-11).

The definitive analysis will be expressed in a risk table to show the frequency of spontaneous abortions by AFSC, the rate of abortion within each group and the relative risk of abortion comparing the OR nurse (9736) with the nonexposed psychiatric nurse (9726) and the nurse anesthetist (9746) with the psychiatric nurse. I expect to be able to determine if exposure to waste anesthetic gases increases the incidence of spontaneous abortion by using this risk ratio (Table 12).

I will also display a frequency table of spontaneous abortions by years of exposure to waste anesthetic gases prior to pregnancy in an effort to determine if a cumulative effect exists (Tables 13 and 14).

Since waste anesthetic gases are suspected to play a role in involuntary infertility I will attempt to establish a fertility index by comparing the number of married female nurses in each AFSC under study with those married nurses who become pregnant each fiscal year (Table 15).

The quality of the data received will be assessed periodically by comparing the date the patient was seen by the physician to the date when the data were received at the Epidemiology Division, by reviewing the completeness and accuracy of the information, and by counting the number of follow-up inquiries for clarification. The efficiency of the

	Married	Single	Total
NAN. (9746)			
ORN (9736)			
PSYN (9726)			

TABLE 3 AGE, P = < .05

	20-29	30-39	40+	Total
NAN. (9746)				
ORN (9736)				
PSYN (9726)				

TABLE 4

RACE, P = < .05

	White	Black	Other	Total
NAN (9746)				
ORN (9736)				
PSYN (9726)				

TABLE 5

PARITY, P = < .05

	0	1	2	3+	Total
NAN (9746)					
ORN (9736)					
PSYN (9726)					

TABLE 6

HISTORY OF PREVIOUS SPONTANEOUS OR THERAPEUTIC ABORTION, P = < .05

	+	-	Total
NAN (9746)			
ORN (9736)			
PSYN (9726)			

TABLE 7

HISTORY OF HYPERTENSION, P = < .05

	+	_	Total
NAN (9746)	l		
ORN (9736)			
PSYN (9726)			

TABLE 8
USE OF I.U.D., P = < .05

	No	< 1 yr	< 3 yr	< 5 yr	> 5 yr	Total
NAN (9746)						
ORN (9736)						
PSYN (9726)						

TABLE 9 USE OF BIRTH CONTROL PILLS, P = < .05

	No	< 1 yr	< 3 yr	< 5 yr	> 5 yr	Total
NAN (9746)						
ORN (9736)						
PSYN (9726)						

	Never	< 1 yr	< 5 yr	< 10 yr	< 15 yr	> 15 yr	Total
NAN (9746)							
ORN (9736)							
PSYN (9726)							

TABLE 11

CURRENT SMOKING HABIT--AMOUNT, P = < .05

	< 1/2 ppd	< 1 ppd	< 2 ppd	> 2 ppd	Total
NAN (9746)					
ORN (9736)					
PSYN (9726)					

TABLE 12 FREQUENCY OF SPONTANEOUS ABORTIONS BY AFSC (RISK TABLE), P = < .05

	+	-	Total	Rate of Abortion per Group =
NAN (9746)	а	b		NAN Rate = $a/a + \frac{1}{2}$
ORN (9736)	С	đ		ORN Rate = $c/c + d$
PSYN (9726)	e	f		PSYN Rate = $e/e + f$

Relative Risk for NAN = af/be

Relative Risk for ORN = cf/de

Relative Risk for both groups overal1 = (a + c) (f)/(b + d) (e)

TABLE 13

DISTRIBUTION OF SPONTANEOUS ABORTION (CURRENT)
PREGNANCY) BY YEARS OF EXPOSURE PRIOR
TO DELIVERY OR OTHER OUTCOME
FOR 9746, P = < .05

	+	-	Total
< 2 yrs			
2 < 5			
5 < 7			
7 < 10			
10 < 15			
> 15			

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TABLE 14

DISTRIBUTION OF SPONTANEOUS ABORTION (CURRENT PREGNANCY) BY YEARS OF EXPOSURE PRIOR
TO DELIVERY OR OTHER OUTCOME
FOR 9736, P = < .05

	+	-	Total
< 2 yrs			
2 < 5			
5 < 7			
7 < 10			
10 < 15			
> 15			

TABLE 15 FERTILITY INDEX = MARRIED PREGNANT IN EACH AFSC/MARRIED IN EACH AFSC FOR EACH FISCAL YEAR, P = < .05

	Pregnant	Not Pregnant	Total
NAN (9746)			
ORN (9736)			
PSYN (9726)			

data input process will be assessed by comparing the date information was received and the date it was keypunched as noted in Figures 4-7.

An information flow diagram (Fig. 8) shows the linkage of File 1 (medical data) with File 2 (personnel data) to form File 3 (epidemiological data). File 3 will consist of a computer file stored on disk (A) and a backup manual file (B) that will contain all the original, manually prepared forms from the originating medical facility, AFMPC, the nurse's consent form, and the coding sheets to be stored in a locked filing cabinet in the data collection office.

File 1--Medical

File 2--Personnel

Source Documents from Med-Source Documents from AFMPC ical Treatment Facility (SF (Personnel Data) 533, SF 88, SF 93, AF 565) Manual Appropriate Information Data Appropriate Information Transcribed to Coding Base - B Transcribed to Coding Sheets Sheets Information Keypunched onto Information Keypunched onto Cards Cards Input of Medical Data Input of Personnel Data Δ Computer Merge File 1 and 2 to Create File 3 Information Stored Offline on Disk to Create Computer Data Base of Epidemiological Data - A Display on Line Printer or CRT as Needed for Followup Computer Process for Data Analysis Decision Point (Determination of Hazardous Effects or Not, Recommendations, if Necessary, to Surgeon General)

Fig. 8. Information system flow chart

CHAPTER III

RESOURCES REQUIRED

This proposal will be submitted for approval by the Air Force prior to implementation. Authorization for funding will be required for six years to complete the study. Since the fiscal year 81 (Oct 80-Sep 81) budget request is probably committed, implementation could be delayed until October 81 in spite of the emphasis the Air Force Surgeon General has placed on the issue of waste anesthetic gas control.

The study packet with information, support, and authorization from the Surgeon General and Chief of the Nurse Corps, and consent forms will need to be duplicated and mailed worldwide to all medical facilities where study subjects are located. We estimate this process to take approximately a month.

Once the study is initiated, the majority of the time for data collection and processing will be expended in transcribing the medical history and personnel data from the source documents onto a coded form for computer input. This process will be assisted by using existing ICDA codes for pregnancy outcomes and the complications for mothers and infants. Alphanumeric codes exist for each Air Force base to assist in

tabulating the assignment history for each nurse. Standardized source documents for the medical data will also aid the transcribers. Unlike other studies, the medical input from the study subjects will not arrive at the data collection site in large numbers or simultaneously, but sporadically. There is also a built-in "lag time" between data input and final data analysis by the very nature of the outcome variable under study. We anticipate a six-month period prior to the start of the study for final preparation and a six-month period after the five-year data collection has elapsed before the team can devote its full time to another project.

All operations for this study will be conducted by the Epidemiology Division, Brooks Air Force Base, Texas. Most of the operational systems and support functions necessary for this study have already been identified among other studies now underway at the division. Some of the resources are in place and functioning. I am not aware of any additional type of resources that would be required. We could utilize existing office space and furniture, telephones, clerical supplies, typewriters, and duplicating machines. The USAF Biometrics Department is located in the Medical Service Center at Brooks. The hub of their computer operation is the PDP 11/70 from the Digital Equipment Corporation. A VT 100 terminal from Digital Equipment Corporation as well as

keypunching equipment is located within the Epidemiology Division.

Disk storage is available.

The amount of computer time, telecommunications, and typewritten correspondence will depend on the subject's willingness to participate in the study and the quality of the data received. Printing and
duplicating costs will be dictated in part by the Surgeon General's
requirements since he will decide those in the reporting chain to
receive the quarterly status reports.

A visual (slides or viewgraphs) presentation on the progress of the study will assist the program director in her periodic briefings to authorized personnel; experts from the Audiovisual and Graphics Department at Brooks will assist with the preparation of these materials.

I have identified the following personnel positions as necessary to implement this study:

<u>Program Director</u>—responsible for the program in its entirety, primary investigator. Suggested position—Nurse Epidemiologist, AFSC 9786.

<u>Program Manager</u>--responsible for plans, programs, physical resources, facilities, manpower, fiscal management, and administrative support. Reports directly to program director. Suggested position--Medical Service Administrator, AFSC 9011.

Data Controller/Programmer--responsible for all aspects of coordination of computer systems support, including forms, input storage systems, product formats, quality control, and methods improvements in coordination with the program director. Suggested position--Computer Officer, AFSC 2685

Computer Technician/Assistant Data Controller/Programmer--will assist the data controller especially in transcribing data from manual files and source documents to a computer input format. Suggested position--Programming Specialist, AFSC 51171.

<u>Secretary or Administrative Specialist</u>--prepares all correspondence; taking draft formats, editing, correcting, and typing copy, assists in general clerical and minor administrative details. Suggested position--GS-4, or AFSC 70250.

I will also consult with the Chief, Epidemiology Division; a representative from the Biometrics Department at Brooks; the Chief of the Obstetrics and Gynecology Department, the Operating Room Supervisor, and the Chief of Anesthesia at Wilford Hall Medical Center for analysis and interpretation of data and recommendations for medical and nursing management should the results of the study indicate adverse effects on personnel.

CHAPTER IV

CONSTRAINING FACTORS AND FACTORS INFLUENCING

INTERPRETATION OF THE STUDY

Stallones identified several recurring problems in the field of industrial epidemiology that are certainly applicable to the study of health effects resulting from exposure to waste anesthetic gases.

Cases tend to occur in small clusters, and the significance of these aggregations in time and space is difficult to assess. Often the relative risks which are observed are low, or populations within which the cases occurred are small, or both. A long latent period may ensue between exposure and clinical manifestation. Exposure is likely to involve a variety of substances both at a given time and over a period of time. A significant proportion of the work force disappears from view. (1979:205)

In an earlier article Dr. Stallones stated that additional complications can arise when workers are spread over a number of sites and when they migrate from one company to another or from job to job or if you were to compare it with the Air Force, from base to base or from one AFSC to another (1976:33). He states further:

To properly assess the association between work and illness we need to be able to compute specific incidence rates. That is, the records systems must not only record illness, but must maintain an account of persons exposed to potentially dangerous situations. Despite our understandable reluctance to establish dossiers and linked record files on individuals, these procedures cannot be as useful as they should be unless the opportunity exists to merge

experience across companies throughout an industry and to trace individuals as they move.

It is precisely our intent to establish a computerized epidemiological data base from both the medical and personnel systems as he suggested. We hope to be better able to manage the five problems identified by Dr. Stallones, especially in reducing the number of study participants who would be lost if it were not for our retrieval system.

Potential selection biases were identified earlier in chapter two. These factors as well as the relatively small sample size could well represent a significant problem in analysis interpretation as noted by Dr. Stallones. He did offer two suggestions that we might incorporate at a later date if these problems do surface.

The difficulty with small numbers can often be overcome by combining the experience of different companies, since this may be viewed as a replicated experiment. The confounding of exposures may also be unraveled by pooling experience industry-wide, for one may be able to establish an exposure matrix and thereby sort out exposures that are important from those that are not. (1979:205)

We may be able to overcome any difficulties in analysis due to sample size or confounding exposures by expanding this study to include Army and Navy nurses in the same career specialties.

A significant determinant of the outcome of the study is the participation and cooperation of both the physician health provider and the nurse/patient. It is a departure from current policy to send any medical records outside the treating hospital unless the patient

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requires a consultation from a provider at another medical treatment facility. We hope to reduce resistance to this temporary change by utilizing standard forms the physician must complete routinely and by providing self-addressed envelopes and postcards for inquiries or brief responses.

We hope to encourage participation and cooperation in both groups by publishing an endorsement for the importance of the study by the Air Force Surgeon General and the Chief of the Nurse Corps in the Medical Service Digest (a health issues magazine distributed quarterly in the Air Force) prior to implementation of the study and periodically throughout the period of study if warranted by a low response rate. A similar letter will appear in the study information packet as mentioned earlier.

We may be able to determine our response rate by utilizing the Nurse Assignments Branch at AFMPC since they can identify pregnant nurses if they receive input from the chief nurse at the hospitals involved. For example, the chief nurse will notify a representative in the assignments branch in order that any pending assignment action be delayed until after the termination of the pregnancy, or she may also consult the assignments branch if complications or duty restrictions have resulted to request supplemental staffing through command channels.

Two critical reviews of the EPA's Alsea II study published in 1979 illuminate several limitations in study design and data analysis that I have recognized and attempted to minimize. The Oregon State University study states:

Most ecological and sociological data come from observational studies in which experimental controls cannot be exercised. The mechanics of analysis of such data may be the same as that of formal experiments, but the inferences are substantially different. For example, associations may be proven from observational data, but causality of an observed association may be inferred only by assumption. In such cases all possible alternative explanations of the association must be examined. If they can be rejected, the explanation by causality is more tenable, but it still is not proven. It is proper to use observational studies to pose hypotheses, and to express the results only in terms of the identified associations. (p. 4)

This investigator recognizes the potential limitations of the study design to be employed and proposes to report the relationship of exposure to waste anesthetic gases and an increased incidence of spontaneous abortion.

Other factors that have been shown to have an association with an increased risk of spontaneous abortion will be collected. By developing panels from the exposed group and the nonexposed group matched on such variables as smoking, previous history of spontaneous or therapeutic abortion, use of birth control pills, hypertension, various metabolic or infectious diseases, and Rh incompatibility it may be possible to infer a causal association.

The major criticisms of the Alsea II study centered on the quality of hospitalized spontaneous abortion data and the variations in medical practice in the areas studied. The authors point out that approximately 12 to 25 percent of pregnancies carried through the first month abort spontaneously during the first half of pregnancy. In the United States, the hospitalization rate for spontaneous abortions is normally about 8 percent. Dr. Lamm believes that this low figure is due to several facts:

- 1. Whether the woman recognizes the event as a miscarriage;
- How anxious the woman is about the abortion and the social support system her lifestyle provides her;
- 3. Whether the woman is financially able to secure treatment;
- 4. Whether the treating physician is a specialist who deals regularly with spontaneous abortion cases;
- 5. The availability of treatment in an outpatient clinic;
- 6. The standard of health care in the community;
- 7. The gestational age of the conceptus and the completeness of the abortion. (pp. 6-7)

The majority of Dr. Lamm's constructive criticisms are minimized by studying a military nursing population which has not been previously reported in the literature. Since the subjects are nursing personnel, they should be aware of the signs and symptoms of spontaneous abortion and will be more alert since it will be an outcome under study. Although the nurses under study receive a salary that would enable them to seek treatment anywhere, it is anticipated that they will utilize the Air Force facilities. The policy regarding medical

care for active duty nurses is relatively uniform in that they are routinely hospitalized. In the event that the abortion is complete and the physician would choose not to admit the patient she would probably convalesce at home and an AF Form 565 utilizing the ICDA code would still be completed so data would not be lost. However, I recognize that the nurse's marital status may have an influence on Lamm's second factor which we may not be able to control. By studying this population under these circumstances, the issues of medical practice variability, sensitivity to the possibility of spontaneous abortion, and the limitations associated with economic restraints, criticism should be minimized.

CHAPTER V

RECOMMENDATIONS, APPLICATION OF THIS

MODEL FOR FUTURE RESEARCH

Should our study show a greater incidence of spontaneous abortion in the exposed group as compared to those not exposed, we would consult with the Chief, Obstetrics and Gynecology, Operating Room Supervisor/Consultant, and the Chief of Anesthesia Services at Wilford Hall Medical Center to assist in recommending specific policies to the Air Force Surgeon General that would reduce exposure to the high risk groups in particular.

The increased risk might justify significant efforts to reduce exposures by improved ventilation systems and to improve or install waste anesthetic gas scavenging systems where they are deficient. A positive finding would also indicate a need for increased emphasis on improving anesthesia work practices to reduce the waste gas emissions in the operating room since the NIOSH document reported that 94-99% of emissions in a scavenged operating room resulted from poor anesthetist/anesthesiologist technique. Educational programs could be developed for use at the School of Anesthesia, Wilford Hall Medical Center and at

periodic seminars such as the American Association of Nurse Anesthetists' annual convention or the Air Force Association of Nurse Anesthetists' annual meeting.

It is suspected that waste anesthetic gases may play a role in mutagenesis, teratogenesis, and carcinogenesis. Haas and Schottenfeld suggest that surveillance of spontaneous abortions could be a useful method of environmental monitoring. They state more specifically:

The relationship between mutagenic, teratogenic, and carcinogenic effects in the offspring of persons exposed to noxious environmental agents is a complex one. Surveillance of spontaneous abortions may have a number of advantages as a prospective means of monitoring for such effects since defective conceptions are aborted selectively. As a result, studies of teratogenesis focusing on spontaneous abortion may be considerably more efficient than those conducted in newborns.

Because the frequency of abnormalities is higher in spontaneous abortions, the sample size needed to demonstrate a change in risk is much smaller than that required for a parallel query addressed to defects recognized at birth. The magnitude of this difference can be dramatic. If chromosomal defects diagnosable on the appearance of the newborn are considered alone, the sample size required may be hundreds of times that required in an investigation examining prevalence of chromosomal anomalies in early abortion. In addition to sample size considerations, study of spontaneously aborted conceptions offers a lead time of at least six months over studies of live births. The abortion specimen can be studied with care and thoroughness, permitting detection of anomalies lethal to the fetus which might escape detection in studies of live births. (1979:612)

With the computerized file of cohorts available from this study, additional research for other variables could be initiated. The epidemiological data collection methods used in this study could serve as

the model for other studies to evaluate the exposures to other suspected hazardous substances in other career fields.

APPENDIX

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Ruth L. Nancarrow was born in Harrisburg, Pennsylvania, on 12 November 1946, the daughter of Hope Dunmire Nancarrow and William Thomas Nancarrow. She was a member of the first graduating class of Central Dauphin East High School in suburban Harrisburg in 1964, after which she entered Harrisburg Polyclinic Hospital School of Nursing. Upon graduation 7 September 1967, she was employed by her alma mater as a staff nurse in the operating room. Ruth was commissioned a Second Lieutenant in the United States Air Force Nurse Corps on 20 August 1968, entering active duty in January 1969. She served as a staff nurse in the operating room at Carswell Air Force Base, Texas, and Cam Ranh Bay, Vietnam. While employed as an operating room and central supply supervisor at George Air Force Base, CA, she completed the requirements for a bachelor of arts degree in special studies and psychology at the University of Redlands August 1974. She served three years as a USAF nurse recruitment officer in Syracuse, NY. Prior to her enrollment in The University of Texas School of Public Health, she was assigned as the Operating Room, Central Supply and Surgical Clinic Supervisor at Altus Air Force Base, OK. During her tour there she completed a master of arts degree in human relations and management from Webster College in May 1979. She was promoted to the rank of major on 1 March 1980.

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